IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

VICTORIA CERVENY, CHARLES CERVENY and ALEXANDER CERVENY, Plaintiffs, vs. AVENTIS, INC., Defendant.	ORDER ON DEFENDANT'S MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT Case No. 2:14-cv-00545

Before the Court is Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint [Dkt. 10]. A hearing on the motion was held on May 27, 2015 at which Plaintiffs were represented by Eric D. Barton and Defendant was represented by Eric A. Swan and Shawn McGarry. Having considered the parties' legal briefs, oral argument and the relevant facts and law, the Court enters this Order granting in part and denying in part Defendant's motion.

Plaintiffs assert various causes of action arising from their allegation that Plaintiff Alexander Cerveny's birth defects were caused by the prescription fertility medication Clomid, manufactured by Defendant, which his mother, Plaintiff Victoria Cerveny, took prior to becoming pregnant with Alexander. Defendant's motion requests that several of the alleged

causes of action be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6).

Strict Liability Design Defect
(Count I)

Under Utah law, manufacturers of prescription drugs are immune from strict liability design defect claims. *Schaerrer v. Stewarts Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003). Utah applies the principles of Restatement (Second) of Torts, §402A, comment k (1965) which provides an exception to strict liability design defect causes of action when a product is determined to be "unavoidably unsafe." *Id.; Grundberg v. Upjohn Co.*, 813 P.2d 89, 95 (Utah 1991). Comment k states:

> *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . .Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

The Utah Supreme Court has deemed prescription drugs "unavoidably unsafe" for purposes of design defect claims. *Schaerrer*, 79 P.3d at 928 ("under Utah law, comment k shields manufacturers and sellers of prescription drugs from strict liability based on allegations of a design defect."); *Grundberg*, 813 P.2d at 95. Because Clomid is a prescription medication, Defendant's motion is hereby GRANTED and this cause of action is dismissed with prejudice.

Manufacturing Defect
(Counts II and VI)

Plaintiffs allege strict liability and negligent manufacturing defect claims. The gravamen of a manufacturing defect claim is "defective execution of the design." *Wankier v. Crown Equip. Corp.*, 353 F.3d 862, 867 (10th Cir. 2003). In order to plead and prove a manufacturing flaw, Plaintiffs must show that the medication Victoria Cerveny ingested was defective as a result of a mistake in the manufacturing process. *Id.* Plaintiffs have not asserted any facts to support a manufacturing defect. The Court finds that under Federal Rule of Civil Procedure 8, the allegations in the First Amended Complaint are insufficient to sustain these causes of action. Defendant's motion is GRANTED and these claims are dismissed without prejudice.

Failure to Warn
(Counts III and VI)

Plaintiffs allege strict liability and negligent failure to warn causes of action arguing Defendant failed to adequately warn both Victoria Cerveny's doctor and Victoria Cerveny herself about the risks of taking Clomid. However, under Utah law, a manufacturer of a prescription medication has no duty to warn the consumer directly. *See Downing c. Hyland Pharmacy*, 194 P.3d 944 (Utah 2008); *Schaerrer v. Stewarts Plaza Pharmacy, Inc.*, 79 P.3d 928 (Utah 2003). Utah has adopted the "Learned Intermediary Doctrine" which holds that a physician "acts as a learned intermediary between the drug manufacturer and the patient." *Schaerrer*, 79 P.3d at 928. Defendant's only duty is to adequately warn the prescribing physician. *Downing*, 194 P.3d at 946-47. Plaintiffs' causes of action based on Defendant's duty to warn Victoria Cerveny's

physician are not at issue in this motion. Defendant's motion regarding the failure to warn Victoria Cerveny directly, both under strict liability and negligence, is GRANTED and those allegations are dismissed without prejudice.

Punitive Damages
(Count VII)

Utah law allows punitive damages against a drug manufacturer only if it is "shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the Federal Food and Drug Administration under its regulations." Utah Code Ann. § 78B-8-203. State law claims based on an alleged fraud on the FDA are preempted by federal law. *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348 (2001). Here, there is no dispute that Clomid was approved by the FDA. Because any allegation that would meet the exception under Utah law in this case is preempted by federal law, Plaintiffs cannot maintain a claim for punitive damages against Defendant. Defendant's motion is hereby GRANTED and this cause of action is dismissed without prejudice.

Breach of Express Warranty, Negligent Design,
Negligence Per Se and Unjust Enrichment
(Counts V, VI, X and XI)

In order to survive a Rule 12(b)(6) motion to dismiss, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The "threshold requirement" of Rule 8 is that the complaint must "possess enough heft to show that the pleader is entitled to relief." *Id.* at 557. There must be "more than

an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Causes of action should be dismissed where the facts asserted present only a "sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). The Court finds that Plaintiffs have failed to plead sufficient facts to support their claims for breach of express warranty, negligent design, negligence per se and unjust enrichment. Defendant's motion with regard to these causes of action is GRANTED and they are dismissed without prejudice.

Fraud and Negligent Misrepresentation
(Counts VIII and IX)

The Court finds that the Defendant has not met its burden for a FRCP 12(b)(6) dismissal of Plaintiffs' fraud and negligent misrepresentation causes of action. Therefore, its motion with regard to these claims is DENIED.

DATED this 14th day of July, 2015.

Dee Benson
United States District Judge